K040122

APR 1 4 2004

Attachment 3: 510(k) Summary of Safety and Effectiveness

This special 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Submitter: Mayo Medical Ventures
200 First St. SW
Rochester, MN 55905

Contact Person: Jade Sadosty
Program Manager

Telephone: (507) 538-1352

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Date Prepared: November 17, 2003

Device Name:
Mayo Clinic BC-10 3.0T MR coil

Device Description:
The Mayo Clinic BC-10 magnetic resonance coil is a transmit/receive, high-pass, quadrature coil using the birdcage circuit design.

Indications for Use:
The Mayo Clinic BC-10 3.0T wrist coil will be used in conjunction with several commercially available MRI systems to more accurately image a variety of maladies associated with the hand, wrist, forearm, and elbow. Maladies include, but are not limited to, carpal tunnel syndrome, nerve compression, ligament injuries, tendon abnormalities, and scarring. Its 10cm diameter design governs the specific area of the body, which can be imaged.

Predicate Device:
The predicate devices for this coil include both the MRI Devices 1.5T phased array wrist coil and the GE Signa 1.5T birdcage, high-pass, quadrature T/R head coil.

Feature	Mayo Clinic BC-10	MRI Devices Signa 1.5T
Coil Type	High-pass, quadrature, T/R	Phased array, receive only
Region of Interest	Small extremities < 10cm	Hand and wrist
Compatibility	All Signa 1.5T MR systems	Signa 1.5T with PA option only
Tuning	No external tuning necessary. Coil is optimized for small extremity anatomy.	No external tuning necessary.

Patient Positioning	Overhead or at patient's side	Overhead or at patient's side
Imaging Configuration	High SNR for small extremity imaging with 10cm FOV.	High SNR for hand and wrist imaging with 6cm FOV.

Summary of Studies:
Testing was performed to demonstrate the Mayo Clinic BC-10 performed in accordance with predetermined acceptance criteria and that the safety and reliability of the coil meets/exceeds standards. Details of this testing are included in the abbreviated 510(k) submission for the referenced device (K031119)

Conclusions:
The results of the testing and evaluations referenced above show that the Mayo Clinic BC-10 is substantially equivalent to already approved extremity coils. It is a proven design with well documented clinical, safety, and reliability data from years of use at the Mayo Clinic in Rochester, MN.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

Ms. Jade Sadosty
Program Manager
Mayo Medical Ventures
200 First St. SW
ROCHESTER MN 55902

Re: K040122
Trade/Device Name: Mayo Clinic BC-10 3.0T MR coil
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: January 15, 2004
Received: January 30, 2004

Dear Ms. Sadosty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1: Indications For Use

510(k) Number (if known): K040122

Device Name: Mayo Clinic BC-10 3.0T

Indications For Use:

The Mayo Clinic BC-10 3.0T wrist coil will be used in conjunction with several commercially available MRI systems to more accurately image a variety of maladies associated with the hand, wrist, forearm, and elbow. Maladies include, but are not limited to, carpal tunnel syndrome, nerve compression, ligament injuries, tendon abnormalities, and scarring. Its 10cm diameter design governs the specific area of the body which can be imaged.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040122

Prescription Use ✓
(Per 21 CFR 801.109)